ALAKH LAD

QUALITY ASSURANCE (PHARMA)

I am an experienced Quality Assurance Asst. Manager having more than 12 years in pharmaceutical industry. Having exposure to formulation as well as API industry.
Seeking a full-time position in the field of Pharmaceutical, where I can apply my knowledge and skills for continuous improvement.

SKILLS

- **Regulatory Compliance:** Expertise in navigating FDA, EMA, and other regulatory guidelines
- **Quality Management Systems (QMS):** Proficient in implementing and maintaining QMS, including CAPA, change control, and document management, to ensure product quality and safety.
- **Risk Management:** Strong ability to conduct risk assessments and develop mitigation strategies to minimize quality-related issues throughout the product lifecycle.
- **Audit and Inspection Readiness:** Experience in preparing for and managing internal and external audits, ensuring all processes meet compliance requirements and industry best practices.
- **Data Analysis and Reporting**: Skilled in utilizing statistical analysis and quality metrics to identify trends, improve processes, and communicate findings to stakeholders effectively.

EDUCATION

BACHELOR OF PHARMACY

Sumandeep Vidyapith University Piparia Vadodara

EXPERIENCE

ASST.MANAGER QUALITY ASSURANCE

Virdev Intermediates Pvt.Ltd. Palsana, Surat

13/06/2024 to till date

- To manage and ensure the quality management system activities are followed.
- Proper documentation is to be followed
- Quality Risk Management to be carried out for controlling the risk related to product.
- Review and approval/Release of Raw Materials (RM), Packaging Materials (PM), Intermediates and Finished Goods (FG) specifications
- Review and approval of Batch records.
- Review of Site Master File, Master validation Plan for any changes.
- Release or rejection of Active Pharmaceutical Ingredients (APIs).
- To investigate the market complaints, OOS (out of specification), OOT (out of trend)., deviation, incident, non-conformance, product recall, reprocess, online rejection, return etc and to suggest and implement methods to avoid reoccurrence.
- To approve quality management documents.

- Internal / External audit to be carried out and timely proper response and CAPA are to be provided.
- To handle regulatory & customer audits.
- To handle SAP activity related to QA.

ASST. MANAGER QUALITY ASSURANCE

Globela Pharma Pvt. Ltd. Sachin, Surat

01/09/2023 to 01/06/2024

- To enhance and implement the Quality assurance system in order to achieve Quality standard
- To motivate and train the sub-ordinates and colleague to improve quality system and current GMP/GLP/GDP/GEP standards in the plant
- To ensure that training conducted as per schedule and relevant records maintained.
- To remain updated regarding the recent international and regulated guidelines.
- To establish, lay down, implement and approve various systems, SOPs and documentation as per current GMP, HACCP systems, safety and regulatory requirements.
- To ensure the plant is in a validated state by ascertaining that the appropriate qualifications and validations are done.
- To monitor document data control in process documents related to manufacturing process.
- Internal / External audit to be carried out and timely proper response and CAPA are to be provided.
- Vendor Qualification activities to be done with proper auditing and documentations activities.
- To ensure all relevant quality related documents are prepared, approved, implemented, and followed.
- Assuring that the right quality products reaches the customer.
- To ensure critical deviations are investigated and resolved.
- To lead the internal audits and external periodically and follow up actions for its compliances.
- To identify gaps and implement quality systems accordingly.
- To conduct vendors audits and evaluate according to the written procedures.
- To investigate the market complaints, OOS (out of specification), OOT (out of trend)., deviation, incident, non-conformance, product recall, reprocess, online rejection, return etc and to suggest and implement methods to avoid reoccurrence.

MANAGER QUALITY ASSURANCE

R. N. Laboratories Pvt. Ltd. Sachin, Surat

21/11/2022 to 25/08/2023

- To manage and ensure the quality management system activities are followed
- Change control are initiated, implemented and closed effectively.
- Deviations are reported and investigated and necessary CAPA are taken.

- Quality Risk Management to be carried out for controlling the risk related to product.
- Proper documentation is to be followed.
- Ensuring the training are imparted.
- Internal / External audit to be carried out and timely proper response and CAPA are to be provided.
- Vendor Qualification activities to be done with proper auditing and documentations activities.
- To ensure all relevant quality related documents are prepared, approved, implemented, and followed.
- Assuring that the right quality products reaches the customer.
- To ensure critical deviations are investigated and resolved.
- To lead the internal audits and external periodically and follow up actions for its compliances.
- To identify gaps and implement quality systems accordingly.
- To conduct vendors audits and evaluate according to the written procedures.
- To guide on validations protocols and execution of validations i.e. Process validation, Cleaning validation, MLT, Analytical Method validation etc.
- Review and approval/Release of Raw Materials (RM), Packaging Materials (PM), Intermediates and Finished Goods (FG) specifications.
- Review and approval of Batch records.
- Review of Site Master File, Master validation Plan for any changes.
- Conduct internal departmental meetings.
- Conduct intra departmental meeting related to quality issues.
- To perform product quality reviews in time.
- To ensure appropriate stability studies are performed and evaluate the stability trend results.
- To ensure that manufacturing and testing equipment’s are appropriately calibrated.
- To ensure that effective change control is followed.
- To ensure that all processes and procedures followed are adequately validated and equipment are adequately qualified.
- Co-ordination with Technical Director for arrangement on major resources and decision.
- Co-ordination with Department Heads and all individuals of Production, Warehouse, Engineering, Quality control, Human Resources.
- Co-ordination with Regulatory Authorities, Vendors and Customers.
- Release or rejection of Active Pharmaceutical Ingredients (APIs).
- To help resolve all quality related complaints in a timely manner.
- To handle product recall if required.
- To responsible for risk analysis activities of all departments.
- To conduct technical trainings and create awareness of current Good Manufacturing Practices (cGMP) / Regulatory requirements.
- To implement, maintain and continuously upgrade quality system in the unit to meet current requirements.
- To ensure compliance on major non-compliance highlighted by regulatory authorities and customer audits.
- To monitor destruction activity of control sample perform on time.
- To handle SAP activity related to QA and ensure all the records are maintained as per defined procedure.

EXECUTIVE QUALITY ASSURANCE

Ami Organics Ltd. Sachin, Surat

05/08/2020 to 17/11/2022

- Handling of Quality Management System activities like:
- Handling of change control, deviation and CAPA management system.
- Impartment of training.
- Handling of market complaint.
- Responsible for Self-inspection / internal audit as per planner.
- Handling of Query and response of customer as well as regulatory audits.
- Handling of out of specification.
- Handling, review and control of Master Documents i.e. SOP, BPR, BCR, Specification, Layouts, Preventive maintenance planner, Instrument schedule etc. and documents verification of engineering department.
- Execution and review of process validation, cleaning validation, equipment qualification and vendor qualification activities.
- Exposed to regulatory audits and compliance like USFDA, WHO, ISO & FDA and other customer audits.

SR. OFFICER QUALITY ASSURANCE

CTX Lifescience Pvt.Ltd. Sachin, Surat

27/01/2016 to 10/07/2020

- To monitor the shop floor activity and do compliance as per GMP.
- Preparation of SOP's and reviewing of Batch record as per process tech pack.
- Reviewing of Validation protocols and reports
- Handling of Deviation, OOS & OOT
- CAPA initiation, implementation & evaluation.
- Handling of change control, evaluation and closing.
- Exposed to regulatory audits and compliance like USFDA, EU, KFDA, WHO, FDA and other customer audits.

OFFICER QUALITY ASSURANCE

Glenmark Pharmaceuticals Ltd. Bharuch, Dahej

April 2015 to January 2016

- Sterile API manufacturing documentation and practices.
- Handling of Quality management systems activities like Deviation, Change control & preparation of process validation protocols and reports
- Cleaning validation protocols and reports.

OFFICER QUALITY ASSURANCE

Gufic Biosience Pvt. Ltd.

January 2012 to April 2015

- Handling of aseptic processes like liquid filling sealing etc. and Document preparation and Manpower handling.

- Preparation processes like washing, sterilization and Operate sterilizer (MHS and DHS) &Filling machine. Equipment validations (M.H.S., D.H.S., Vial washing / filling machines, Lyophilizer) and Process validations, media filling, cleaning validation and area validation.
- Preparation of documents like SOPs, BMRs, Validation Protocols, Validation Reports. Recommend process improvements to enhance production quality and quantity. Aseptic process and area handling.
- Trouble shooting of machine and process and Investigate problems, analyze root causes and define resolutions. Process validations, Equipment qualification, Media filling.
- Have worked on Autoclave, DHS (Washing & Depyrogenation), filling and sealing areas and
- Have done VALIDATION of AUTOCLAVE, DHS & media filling.

EXTRA CURRICULAR ACTIVITIES

- Participated in IPC 2010 held at Nirma University at Ahmedabad.
- ·Got 2nd prize in CHESS competition at university level.
- ·Winner in VOLLEY BALL competition at University Level.

CONTACT

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